



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Novel Therapeutics for the treatment of neurodegenerative disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Neurological Disorders and Stroke (“NINDS”), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to University College London Business, Ltd. (“UCLB”), incorporated in England and Wales under company registration number 02776963 whose registered office address is University College London, Gower Street, London WC1E 6BT, United Kingdom, for NINDS’s rights to the patent applications listed in the Supplementary Information section of this notice. UCLB is the technology transfer company of the University College London (“UCL”), a non-profit research institution located in London, United Kingdom.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Neurological Disorders and Stroke Technology Transfer Office by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Lola Olufemi, Ph.D., Senior Technology Portfolio Manager; NINDS Technology Transfer Office, at Telephone: (301) 451-3748 or E-mail: olufemioo@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed

under the prospective agreement to UCLB include: PCT patent application number PCT/EP2021/084908, entitled “Novel Therapeutics for the treatment of neurodegenerative disorders” (claiming priority to GB 2019418.9, filed December 9, 2020) filed December 9, 2021 (HHS Reference E-198-2021) and GB patent application number 2117758.9, entitled, “Therapeutics for the treatment of neurodegenerative disorders” (HHS Reference E-071-2023), filed December 9, 2021.

With respect to the inventions described and claimed in the patent applications PCT/EP2021/084908 and GB 2117758.9, each of the inventors has assigned their rights to their respective employers or an entity which manages the intellectual property for their employer (The United States of America, UCL and UCLB). The prospective license will be for the purpose of consolidating the patent rights with UCLB, the co-owner of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by UCLB will be subject to the provisions of 37 CFR Part 404.

The technologies describe antisense oligonucleotides (ASOs) that are capable of modulating splicing by preventing inclusion of an UNC13A cryptic exon into an UNC13A mature mRNA. Guide RNAs including the ASO, and viral vectors expressing the ASO are also described. Such ASOs and guide RNAs may be used as a medicament, for example, to treat neurodegenerative disorders, particularly those associated with TDP-43 pathology.

This notice is made pursuant to 35 U.S.C. §209 and 37 CFR Part 404. The prospective exclusive patent license will include terms for the sharing of royalty income

with NINDS from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NINDS receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C 552.

Susan E Ano,

Branch Chief,

Technology Transfer Branch,

National Institute of Neurological Disorders and Stroke.